1.0 510(K) SUMMARY

Applicant Name:	Biomerix Corporation 47757 Fremont Boulevard Fremont, CA 94538 Phone: (510) 933-1222 Fax: (510) 933-3451
Contact Person:	Christina L Kichula Sr. Director, RA/QA/CA
Date Prepared:	May 11, 2010
Device Trade Name: Device Common Name: Classification Name:	Biomerix Ventral Hernia Repair Mesh Polymeric surgical mesh Mesh, surgical, polymeric
Predicate Devices:	• Biomerix Composite Surgical Mesh (K082941) • Ethicon PROCEED Surgical Mesh (K060713) • Apside Surgimesh XB (K072974) • Biomet Mesofol® Surgical Sheet (K062558) • MAST Biosurgery Surgi-Wrap MAST Bioresorbable Sheet (K050332) • Polyganics VivoSorb Sheet (K042811)
Device Description	The Biomerix Ventral Hernia Repair Mesh is a sterile, composite mesh comprised of three layers: 1) a thin sheet of the Biomerix Biomaterial™, 2) a layer of knitted polypropylene monofilament fibers and 3) a resorbable lactide-caprolactone film. The resorbable film separates the permanent mesh from underlying tissues and organ surfaces, and it is designed to minimize the risk of a tissue attachment to the device during the wound healing period. The Biomerix Ventral Hernia Repair Mesh is provided sterile for single use and is available as individually packaged thin sheets in various shapes and sizes.
Intended Use	The Biomerix Ventral Hernia Repair Mesh is intended for the reconstruction of hernias and soft tissue deficiencies and for the temporary bridging of fascial defects. The resorbable protective film minimizes tissue attachment to the device in case of direct contact with the viscera.
Device Technological Characteristics and	The Biomerix Ventral Hernia Repair Mesh is similar in materials, design, performance and intended use to

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Comparison to Predicate Device(s):	other surgical meshes. Any differences in the above characteristics have been adequately tested to support substantial equivalence.
Performance Data:	Bench testing, conducted in accordance with FDA's *Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh (issued March 2, 1999)*, was performed to demonstrate that the device as manufactured meets the performance specifications. Test results demonstrate that the device meets the specifications, performs comparably to predicate devices and is acceptable for clinical use. Biocompatibility testing in accordance ISO 10993-1 standards was conducted, and results demonstrate that the device is biocompatible according to these standards. Animal testing demonstrates that the Biomerix Ventral Hernia Repair Mesh performs equivalently to a predicate device in terms of minimization of tissue attachment to the device and histological response.
Conclusion:	Based on the material, biocompatibility, bench, and animal testing, and the proposed device labeling, the Biomerix Ventral Hernia Repair Mesh is substantially equivalent to the identified predicate devices in terms of intended use, safety, and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Biomerix Corporation
% Ms. Christina L. Kichula
Senior Director, RA, QA & CA
47757 Fremont Boulevard
Fremont, California 94538

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Re: K093123
Trade/Device Name: Biomerix Ventral Hernia Repair Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: April 29, 2010
Received: April 30, 2010

Dear Ms. Kichula:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

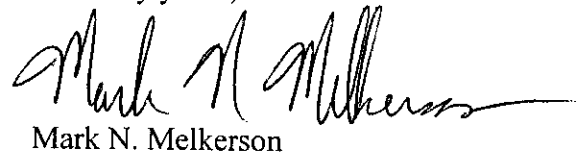
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4.0 INDICATIONS FOR USE

Indications for Use

510(k) Number (if known): K093123

Device Name: Biomerix Ventral Hernia Repair Mesh

Indications for Use:

The Biomerix Ventral Hernia Repair Mesh is intended for the reconstruction of hernias and soft tissue deficiencies and for the temporary bridging of fascial defects. The resorbable protective film minimizes tissue attachment to the device in case of direct contact with the viscera.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MKM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K093123

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